AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q96125

Application No.: 10/587,398

**REMARKS** 

The Amendment, filed in response to the Office Action mailed June 26, 2009, is believed to fully address all and every issue raised in the Office Action. Favorable reconsideration on the merits and allowance of the application are respectfully requested.

Claims Disposition and Summary of Amendments

Claims 1-5 and 7-34 are all the claims pending in the application. Claims 7, 8, and 12-32 are withdrawn from consideration as being drawn to non-elected invention. Claims 1-5, 9-11, 33, and 34 are examined on the merits. Claims 1-5, 9-11 and 34 are amended in order to address objections and improve wordings.

In the Amendment, the corrections of units from "mg/Ml" to "mg/l" may be supported by the disclosure of page 10, line 1 of the specification citing Catalog Number 12800-017 for "high glucose DMEM." Applicant also submits under a separate transmittal letter a copy of the Catalog Number 128000-017. As this submission is made in support of Applicant's arguments which are made in response to the Office Action, and, thus, no Information Disclosure Statement is required.

Similarly, the units "mg/ml" and "cells/cm<sup>2</sup>" are corrected to "ng/ml" (supported by the disclosure, among others, at page 19, line 31 of the specification) and "cells/ml." The conversion from "cells/cm<sup>2</sup>" to "cells/ml" is based on the description of a reference, "R. Ian Freshney, "Culture of Animal Cells: A manual of Basic Technique," 4<sup>th</sup> ed., Wiley 2005, p.

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186), of which copy is submitted under a separate transmittal letter. As shown in Freshney reference, 1 cm<sup>2</sup> of medium corresponds to 0.2 ml.

No new matter is introduced and entry of the amendment is respectfully requested.

### **Information Disclosure Statements**

To date three Information Disclosure Statements have been filed;

- 1) July 27, 2006;
- 2) February 18, 2009; and
- 3) August 4, 2009.

The Examiner has returned PTO/SB/08 forms filed on July 27, 2006, and February 18, 2009, but has only considered M. Reyes et al. However, it is believed that the Information Disclosure Statement filed on August 4, 2009, provides the needed information for the Examiner to review all of the references cited to date. Specifically,

-a copy of English language WO 03/070922, was filed on February 18, 2009. It is also listed on August 4, 2009 as corresponding to KR 2003-0069115 listed on July 27, 2006, and visa versa.

-a copy of English language WO 03/068937 was filed on August 4, 2009;

-a copy of English language WO 02-064755 was filed on August 4, 2009.

Accordingly, it is respectfully requested that the Office consider and return an initialed copy of the SB/08 Form submitted on August 4, 2009.

### **Election/Restrictions**

Applicant thanks the Examiner for considering claims 1-4 and 9-11, in light of Applicant's traversal that the common technical feature contributes over the art references.

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Applicant respectfully requests that, if elected and examined claims are found allowable, claims which recite all elements of the allowable claims be examined on the merits in this application.

### **Response to Claim Objections**

Claims are objected to various reasons as stated on page 3 of the Action.

In response, the claims and the specification are amended to correct typographical errors and/or improved English wordings, rendering the objection moot.

# Response to Claim rejections under 35 U.S.C. 112, first paragraph:

In the Office Action, claims 1-5, 9-11, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

In this regard, the Office admits that, page 20, lines 15-21, of the specification include a working example describing the multipotent progenitor/stem cells yielded by steps encompassed by the steps in the claims, in particular the multipotent progenitor/stem cells isolated and cultured from the cord bloodderived mononuclear cells according to the method of the present invention indeed showed the immunophenotype profile having positive reactions against antibodies for CD 14, CD31, CD44, CD45 and CD54 antigens; negative reactions against antibodies for CD34, CD49a, CD62E, CD73, CD90 and CD133 antigens; and partial positive reactions against antibodies for CD104, CD105 and CD166 antigens. See pages 4-5 of the Action. Regarding claims 1-4, 9-11, 33, and 34, the Office argues they lack written description for a similar reason, for example, claims 9-11 require the cell of claim 5 as a starting material.

Without acquiescing or commenting on the rejections, solely in order to advance the prosecution, claim 5 is amended to the scope which the Office admits to comply with the written

description. Amendment to claim 5 is supported by the description of page 20, lines 15-21 of the English text.

Accordingly, the rejection of claims 1-5, 9-11, 33, and 34 under 35 U.S.C. § 112, first paragraph is rendered moot and withdrawal is respectfully requested.

# Response to Claim rejections under 35 U.S.C. 112, second paragraph:

In the Office Action, claims 1-5, 9-11, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the recitations "a cord blood-derived mononuclear cell," "supplementary elements," in claims 1 and 5, and other claims are rejected. The recitations "positive and partial positive," "negative and partial negative," and "negative and partial positive" reactions in claim 5 are pointed out. Claim 34 is rejected because it does not recites a positive, active step involved in the recited use as well as it recites "and" for recited diseases.

In response, claims are amended as shown above, rendering the rejection moot.

## Response to Claim Rejections under 35 USC § 101

In the Office Action, claim 34 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process.

Claim 34 is amended to recite an active, positive step, rendering the rejection moot.

## Response to Claim Rejections under 35 USC § 102

In the Office Action, claims 5, 33, and 34 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Luderer et al. (1980, U.S. Patent 4,190,535; reference A) taken in

light of Reid et al. (2005, U.S. Patent Application Publication 2005/0148072; reference B) and Atala (2003, U.S. Patent Application Publication 2003/0211602; reference C).

The Office interpret claims, in the interest of compact prosecution, as being drawn to a cell that shows positive reactions against antibodies for CD14, CD31, CD44, and CD45 and negative reactions against antibodies for CD34, CD62E, CD90, and CD133.

Luderer is relied upon as teaching isolated monocytes (column 2, lines 23-34; and column 5, line 44, through column 6, line 52).

Reid is cited solely as evidence that CD14 and CD31 are markers of monocytes and CD44 and CD45 are markers of leukocytes (of which monocytes are a subset). Reid further teaches that CD54 is a marker of endothelial cells and CD62 is a marker of platelets (paragraph 320).

Atala is cited solely as evidence that CD90 is a marker of mesenchymal stem cells, and CD133 is a marker of hematopoietic stem cells (paragraph 32)

The Office asserts that the monocytes of Luderer, because they are monocytes, by definition express monocyte markers (CD14, CD31, CD44, and CD45) and do not express markers of disparate cell types (e.g, endothelial cells, platelets, MSCs, and HSCs; CD54, CD62, CD90, and CD133, respectively). The Office further kindly suggest that this rejection would be overcome by amending the claims such that they particularly require the cell to express a combination of markers that are not expressed exclusively by monocytes.

Without acquiescing or commenting on the merits of the rejections, solely in order to advance the prosecution, claim 5 is amended discussed above, to recite that the multipotent progenitor/stem cells have an immunophenotype profile showing positive reactions against antibodies for CD14, CD31, CD44, CD45, CD54, CD104, CD105, and CD166 antigens; and

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negative reactions against antibodies for CD34, CD49a, CD62E, CD73, CD90, and CD133 antigens, rendering the rejection moot.

None of the cited references disclose the multipotent progenitor/stem cell of the subject invention which shows for the first time positive reactions against the antibodies for all four antigens CD14, CD31, CD54, and CD105.

Accordingly, it is believed that the subject invention defined in claim 5 and claims 33 and 34 reciting claim 5 are novel over the prior art references. Withdrawal of the rejections and allowance of the application are respectfully requested.

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**CONCLUSION** 

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number 202-775-7588.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

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